IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

U.S. Patent No. 7,138,501

Confirmation No. 5654

Patentee: Ruben et al.

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Docket No.: PF523P1

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

MEMORANDUM IN SUPPORT OF PETITION TO INVOKE THE SUPERVISORY AUTHORITY OF THE DIRECTOR (37 C.F.R. § 1.181(a)(3)) AND/OR OF PETITION FOR SUSPENSION OF 37 C.F.R. § 1.705(d) (37 C.F.R. § 1.183)

This Memorandum is submitted by Petitioner in support of the accompanying "PETITION TO INVOKE THE SUPERVISORY AUTHORITY OF THE DIRECTOR (37 C.F.R. § 1.181(a)(3)) AND/OR PETITION TO SUSPEND 37 C.F.R. § 1.705(d) (37 C.F.R. § 1.183)." Petitioner also submits herewith the following documents: (a) "REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT (37 C.F.R. § 1.705(d))" and (b) "STATEMENT OF THE CORRECT PATENT TERM ADJUSTMENT."

REASON FOR THE PETITION

Because the Federal Circuit in *Wyeth v. Kappos* overruled the United States Patent and Trademark Office ("USPTO") interpretation of 35 U.S.C. § 154(b) ("section 154"), Petitioner seeks to invoke the supervisory authority of the Director to reconsider and correct the patent term adjustment for U. S. Patent No. 7,138,501 (hereinafter "the '501 patent," which is provided herewith as Exhibit A) under 37 C.F.R. § 1.181(a)(3) ("Rule 181(a)(3)") and/or requests suspension of the two-month time deadline of 37 C.F.R. § 1.705(d) ("Rule 705(d)") for reconsideration and correction of the patent term adjustment of the '501 patent. *See Wyeth v. Kappos,* 591 F.3d 1364 (Fed. Cir. 2009).

Under the Federal Circuit's interpretation of section 154(b), Petitioner is entitled to an additional 381 days of patent term adjustment. The Director's method of calculation of patent term adjustment for the '501 patent is clearly erroneous because it is contrary to the Federal Circuit's holding in *Wyeth*. This is an extraordinary situation because the Federal Circuit overruled the USPTO interpretation of section 154(b) after the '501 patent had issued, such that Petitioner had no appropriate opportunity to seek reconsideration of its patent term adjustment on that basis. Justice requires granting this petition because Petitioner has no other routes for administrative relief to correct the patent term adjustment of the '501 patent under section 154(b).

STATEMENT OF FACTS

The application for the '501 patent was filed on June 15, 2001, and issued on November 21, 2006. Delay under both 35 U.S.C. § 154(b)(1)(A) ("A" delay) and 35 U.S.C. § 154(b)(1)(B) ("B" delay) occurred during prosecution.

There were five instances of "A" delay.

The first "A" delay occurred from the day after fourteen months from the filing date (i.e., from August 16, 2002) to the mailing of the restriction requirement (i.e., until May 7, 2003). The first delay totals 265 days.

The second "A" delay occurred from the day after four months from filing a response to the restriction requirement (i.e., November 8, 2003) to the mailing of the first office action (i.e., until September 14, 2004). The second delay totals 312 days.

The third "A" delay occurred from the day after four months from filing a response to the first office action (i.e., from April 15, 2005) to the mailing of the final office action (i.e., until May 4, 2005). The third delay totals 20 days.

The fourth "A" delay occurred from the day after four months after filing a response to the final office action (i.e., from December 5, 2005) to the mailing of a notice of allowance (i.e., until December 21, 2005). The fourth delay totals 17 days.

The fifth "A" delay occurred from the day after four months from paying the issue fee (i.e., from July 21, 2006) to the issuance of the '501 patent (i.e., until November 21, 2006). The fifth delay totals 124 days.

Thus, the "A" delay amounts to 738 days.

"B" delay also was accrued during prosecution. The "B" delay occurred from the day after three years from the filing date (i.e., from June 16, 2004) to the issue date (i.e., until November 21, 2006). The "B" delay amounts to 889 days.

The total of the USPTO "A" delay and "B" delay amounts to 1627 days (i.e., 738 days + 889 days). However, some of the "A" delay occurred after the "B" delay began on June 16, 2004, i.e., some of the "A" delay overlaps with the "B" delay in the time period after June 15, 2004. *See* 37 C.F.R. § 1.703(f).

In particular, the first "A" delay discussed above (i.e., 265 days) and the portion of the second "A" delay discussed above up until the beginning of the "B" delay after June 15, 2004 (i.e., 221 days) do not overlap with the "B" delay period. The remaining "A" delays overlap with the "B" delay period, including the portion of the second "A" delay discussed above after June 15, 2004 (i.e., 91 days), the third "A" delay (i.e., 20 days), the fourth "A" delay (i.e., 17 days), and the fifth "A" delay (i.e., 124 days). Thus, there were 252 days of overlap of "A" and "B" delays.

Accordingly, the total USPTO delay amounts to 1375 days (i.e., 1627 days minus 252 days).

Applicant delay amounts to 240 days (37 C.F.R. § 1.704(a)) based on the following periods of delay: (a) a delay of 151 days from the filing of a reply to an office action on July 7, 2003, to the submission of an information disclosure statement on December 5, 2003 (37 C.F.R. § 1.704(c)(8)), (b) a delay of 35 days from the filing of a reply to an office action on December 14, 2004, to the submission of a clean copy of the substitute specification on January 18, 2005 ((37 C.F.R. § 1.704(b)), and (c) a delay of 54 days from the filing of an after-final reply on August 5, 2005, to the submission of a supplemental after-final reply on

September 27, 2005 (37 C.F.R. § 1.704(b)). *See* Petition for Patent Term Adjustment and Decision Granting Petition for Patent Term Adjustment (Exhibits B and C, respectively).

Accordingly, the correct patent term adjustment for the '501 patent is 1135 days (i.e., 1375 days of USPTO delay minus 240 days of Applicant delay). The face of the '501 patent and the Issue Notification for the '501 patent incorrectly state that the Patent Term Adjustment is only 754 days, i.e., 381 days fewer than the patent term adjustment properly attributable to the '501 patent. *See* '501 patent (Exhibit A) and Issue Notification (Exhibit D). Petitioner did not seek reconsideration of the patent term adjustment determination after the issuance of the '501 patent.

ARGUMENT

I. PATENT TERM ADJUSTMENT MAY INCLUDE BOTH "A" AND "B" DELAYS

Under 35 U.S.C. § 154(a)(2), a patentee is entitled to a patent term of 20 years from the date of filing. 35 U.S.C. § 154(b)(1)(A) guarantees an adjustment of patent term for each day the USPTO delays in responding to certain patentee filings ("A" delay). Additionally, patent term adjustment is guaranteed for every day a patent is pending after three years from the filing date under 35 U.S.C. § 154(b)(1)(B) ("B" delay). Section 154(b) prohibits double-counting of time:

> To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

35 U.S.C. § 154(b)(2)(A). The USPTO interpreted this portion of section 154(b) in the following manner:

> [I]f an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B), *the entire*

> *period during which the application was pending before the Office* (except for periods excluded under 35 U.S.C. § 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, *is the relevant period under 35 U.S.C. § 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. § 154(b)(2)(A).*

69 Fed. Reg. 34238 (2004) (emphasis added). In sum, when an application approved for issue was pending for more than three years, the USPTO treated the "A" delay and the "B" delay as overlapping, such that an applicant could get credit for *either* an "A" delay or a "B" delay, but not both.

A recent decision of the Federal Circuit overturned this USPTO interpretation of the term "overlap" under section 154(b). *Wyeth,* 591 F.3d at 1372. The Federal Circuit held that the USPTO's interpretation could not be reconciled with the plain language of the statute. *Id.* For example, under the USPTO interpretation, an application is "*delayed* under [the B guarantee] during the period *before it has been delayed.*" *Id.* at 1370 (emphasis in original). The *Wyeth* court rejected the USPTO interpretation and instead held that "the language of section 154(b) does not even permit B delay to start running until three years after the application is filed." *Id.* Accordingly, the Court held that if "an A delay occurs on one day and a B delay occurs on a different day, those two days do not "overlap" under section 154(b)(2)." *Id.* At 1370.

Thus, under *Wyeth*, patentees are entitled to both "A" and "B" delays as long as the two delays do not occur on the same calendar day.

II. PETITIONER IS ENTITLED TO AN ADDITIONAL 381 DAYS OF PATENT TERM ADJUSTMENT

Because the USPTO's interpretation of "overlap" in section 154(b)(2)(A) has been overruled by the Federal Circuit in *Wyeth*, Petitioner is entitled under to an additional 381 days of patent term adjustment under section 154(b)(1)(B). *Id* at 1372.

Petitioner was not granted the correct patent term adjustment because the USPTO failed to include the "A" delay in its patent term adjustment. Instead, Petitioner was only granted 754 days of patent term adjustment apparently arising from "B" delay that occurred between the date that was three years after the filing date (i.e., from June 16, 2004) and the issue date (i.e., until November 21, 2006) minus Applicant delay.

As discussed in detail above, the "A" delay totaled 738 days, while the "B" delay totaled 889 days. The overlap of "A" and "B" delay as properly determined in view of the *Wyeth* decision is 252 days. Thus, the total USPTO delay is 1375 days (i.e., 738 days + 889 days minus 252 days). Applicant delay totaled 240 days. Accordingly, the correct patent term adjustment is 1135 days (i.e., 1375 days minus 240 days), which is significantly different than the 754 days of patent term adjustment incorrectly recited on the face of the '501 patent (Exhibit A) and on the Issue Notification (Exhibit D).

Under normal circumstances, when a patentee disputes a determination of patent term adjustment reflected on an issued patent, the patentee files a request for reconsideration under 37 C.F.R. § 1.705(d) within two months of issuance of the patent, as required by 37 C.F.R. § 1.705(d). The period set forth in Rule 705(d) is not extendable. 37 C.F.R. § 1.705(e). Additionally, a patentee dissatisfied with a decision of the Director relating to patent term adjustment may bring a civil action for reconsideration in the United States District Court for the District of Columbia within 180 days after the grant of the patent. 35 U.S.C. § 154(b)(4)(A). However, in this situation where both regulatory and statutory deadlines for reconsideration of patent term adjustment have passed, the patentee has no route for administrative relief other than to petition to invoke the supervisory authority of the Director

under 37 C.F.R. § 1.181(a)(3) and/or petition to suspend the deadline imposed by Rule 705(d) under 37 C.F.R. § 1.183.

III. PETITION TO INVOKE THE SUPERVISORY AUTHORITY OF THE DIRECTOR (37 C.F.R. § 1.181(a)(3))

Petitioner seeks to invoke the supervisory authority of the Director to reconsider and correct the patent term adjustment for the '501 patent in view of the Federal Circuit decision in *Wyeth*. The USPTO's calculation of patent term adjustment for the '501 patent is *clearly* in error under *Wyeth* because the USPTO's calculation does not properly include all of the periods of delay accrued (i.e., the "A" and "B" delays). *Cf. Ex parte Hartley*, 1908 CD. 224, 136 O.G. 1767 (Comm'r Pat. 1908) (a petition under 37 C.F.R. § 1.181, requesting that the Director of the USPTO exercise his supervisory authority and vacate the examiner's decision, will not be entertained except where there is a showing of clear error). In contrast to the Federal Circuit's *Wyeth* holding, the patent term adjustment for the '501 patent only appears to include the "B" delay and not the "A" delay, even though there were periods of non-overlapping "A" delay and "B" delay that occurred during prosecution of the '501 patent. Thus, the USPTO's patent term adjustment for the '501 patent is clearly erroneous because it does not include both the "A" delay and the "B" delay to the extent that they do not overlap on the same calendar day. *See Wyeth,* 591 F.3d at 1370.

Accordingly, this is an appropriate circumstance for the Director to exercise his authority and reconsider and correct the '501 patent's erroneous patent term adjustment.

IV. THE DEADLINE FOR RECONSIDERATION UNDER RULE 705(d) SHOULD BE WAIVED HERE

The waiver of 37 C.F.R. § 1.705(d) is warranted because Petitioner could not have requested reconsideration of its patent term adjustment on the basis of *Wyeth* until after the Federal Circuit's decision (and, indeed, after the USPTO's statement that no appeal would be taken from that decision to the U.S. Supreme Court). As a result, Petitioner could not have acted within the two-month deadline recited in Rule 705(d).

Rule 183 states:

> In an extraordinary situation, when justice requires, any requirement of the regulations in this part which is not a requirement of the statutes may be suspended or waived by the Director . . . on petition of the interested party, subject to such other requirements as may be imposed. . . .

37 C.F.R. § 1.183. For a grant of waiver of the rules, a petitioner must establish (1) that there was an extraordinary situation where (2) justice requires waiver of the rules.

A. A Radical Change In the Interpretation Of Federal Regulations Is An Extraordinary Situation

The *Wyeth* decision has overruled a crucial USPTO interpretation of section 154(b). *Wyeth*, 591 F.3d at 1372. Under the correct interpretation of section 154(b), Petitioner is entitled to a significant additional patent term adjustment. This is an extraordinary situation because no amount of due care would have enabled Petitioner to request reconsideration on the basis of the *Wyeth* decision within the deadline imposed by Rule 705(d).

B. The Interests of Justice Would Be Served by Suspending the Two-Month Deadline of 37 C.F.R. § 1.705(d)

Because Petitioner's '501 patent issued too far in advance of *Wyeth*, Petitioner had no means of obtaining a correct patent term adjustment under section 154(b)(3) via an administrative route within the USPTO within the time limit recited in Rule 705(d). The Director is required to "provide the applicant one opportunity to request reconsideration of any patent term adjustment determination made by the Director." 35 U.S.C. § 154(b)(3)(B)(ii). Here, the Petitioner effectively lacked the opportunity to request reconsideration of the patent term adjustment made by the Director involving the handling of overlap between "A" and "B" delays because the '501 patent issued too far in advance of the Federal Circuit's *Wyeth* decision, which overruled the USPTO's interpretation of section 154(b).

Since Petitioner's '501 patent granted more than 180 days prior to the Federal Circuit's *Wyeth* decision, Petitioner has no recourse to initiate a civil action against the Director in the United States District Court for the District of Columbia under 35 U.S.C. § 154(b)(4)(A). *See, e.g., Solvay Pharma. GmBH v. Dudas*, 08-cv-02053 (D.D.C.) (seeking reconsideration of patent term adjustment on the basis of *Wyeth*); *Purac Biochem, B.V. v. Dudas*, 08-cv-02067 (D.D.C.); *Biogen Idec Inc. v. Dudas*, 08-cv-02061 (D.D.C.); *Molecular Insight v. Dudas*, 08-cv-02068 (D.D.C.); *Molecular Insight v. Dudas*, 09-cv-02065 (D.D.C.).

Accordingly, justice requires the Director to suspend Rule 705(d), because the USPTO has failed to uphold the statutory guarantees of section 154(b) and Petitioner has no administrative route (other than under Rule 181(a)(3), which also is relied upon herein) to challenge the USPTO's incorrect patent term adjustment.

C. The Director has Authority to Waive 37 C.F.R. § 1.705(d) because It Is Not a Statutory Requirement

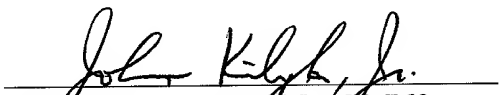
Petitioner seeks waiver of a regulation and not a statutory requirement; therefore, the Director has authority to grant this petition. *Cf. Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.3d 1321 (Fed. Cir. 1998) (Federal Circuit recognized that statutory requirements cannot be waived or suspended under 37 C.F.R. § 1.183); *Howard Florey,* 2008 WL 2674033, at *10-11 (even though it was an extraordinary situation, where petitioner sought suspension of a statute, no relief could be granted). For example, in *Bachler*, the Commissioner granted the request for reconsideration since the subject request involved the timely filing of a brief required by the USPTO rules and not by statute. 229 U.S.P.Q. at 554.

Similarly here, Petitioner seeks suspension of. Rule 705(d), which is a rule created by the Director pursuant to authority granted by Congress in 35 U.S.C. § 154(b)(3)(A). Thus, because Rule 705(d) is a rule – rather than a statute – the Director has the authority to grant this petition under 37 C.F.R. § 1.183 to provide the relief requested herein.

CONCLUSION

The *Wyeth* decision creates an extraordinary situation where Petitioner is entitled to additional patent term adjustment but where, through no fault of its own, Petitioner has no administrative route to request reconsideration within the USPTO other than by way of this petition. For these reasons, Petitioner seeks to invoke the supervisory authority of the Director to reconsider and correct the patent term adjustment of the '501 patent or, in the alternative, requests waiver of the two-month deadline contained in Rule 705(d) and reconsideration and correction of the patent term adjustment of the '501 patent.

Respectfully submitted,



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